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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,687	01/08/1999	FRANCIS P. TALLY	CPI98-03P9MA	7885

7590

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/04/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/227,687	Applicant(s) TALLY ET AL.	
	Examiner Gerald Leffers	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-12,23-27,50-54 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 50-54 is/are allowed.
- 6) ☒ Claim(s) 1,2,7-12,23-27 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

[Handwritten signature]

DETAILED ACTION

Receipt is acknowledged of an amendment (Paper No. 18) and Terminal Disclaimer (Paper No. 17) filed on 9/17/01. Receipt is also acknowledged of a supplemental copy of the sequence listing (Paper No. 19). The Terminal Disclaimer and supplemental copy of the sequence listing appear to be proper and have been entered into the file. In Paper No. 18, applicants have cancelled some claims (claims 3-5, 13-22, 28-49, 55 and 59-66) and amended several other claims (1, 6—8, 11, 23, 50, 56-58).

Claims 1-2, 6-12, 23-27, 50-54, 56-58 are pending in this application. New rejections are made in this action that were not necessitated by applicants' amendments to the claims in Paper No. 18. Therefore, this action is not final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 7-12, 23-27 and 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that there is not clear and positive prior antecedent basis for the term gene in step (b). It would be remedial to amend the claim at step (b) to read "exogenous gene". **This is a new rejection.**

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Claim 7 is vague and indefinite in that it is unclear what is referred to by the term “growth rate” in step (c), line 3. It would be remedial to insert the words “of the cells” following the term “growth rate” at this point in the claim. **This is a new rejection.**

Claim 11 is vague and indefinite in that the outcome of the claim does not necessarily match the intended result recited in the preamble. Claim 11 reads “A method for determining whether a target component ...is essential for growth of said cell...”. However, what is determined by practicing the recited steps of the method is whether a target component is essential for growth of the cell in an animal. It would be remedial to amend both the preamble and final step of the claim to clearly indicate this difference. **This is a new rejection.**

Claim 12 is vague and indefinite in that there is no clear and positive prior antecedent basis in the claim for the term “infection”, making it unclear how identification of an inhibitor of growth for the cell when in an animal necessarily identifies an inhibitor of infection. It would be remedial to amend the claim to more clearly link cell growth and a process of infection. **This is a new rejection.**

Claim 23 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term “a target cell component” in step (e) of the claim, making it unclear how the target cell component relates to the biomolecule expressed in the cell. It would be remedial to amend the claim to more clearly indicate the relationship between the target cell component and the biomolecule which is expressed in the cell and leads to the observed phenotype. **This is a new rejection.**

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Claims 7-8, 10-12, 56-58 are vague and indefinite in that the claims specify “suitable” control animals or cells. **This rejection is maintained for reasons of record in Paper No. 15, mailed 3/13/01 and repeated below.**

The term “suitable” is inherently indefinite in that the criteria for a “suitable” control are likely to vary from investigator to investigator. It would be remedial to amend the claim language to clearly indicate what exactly constitutes a “suitable” control for the recited methods.

Response to Arguments

Applicant's arguments filed in Paper No. 18 have been fully considered but they are not persuasive. Applicants' response essentially argues that the concept of a suitable control is widely taught and known in the art, and that the specification provides several examples of “suitable” control animals or cells. While the concept of using controls in experiments is widely known in the art, this does not mean that what constitutes a “suitable” control is widely accepted. While it is admitted that it might be accepted that the term “suitable” necessarily includes, at a minimum, a standard for a single variable to be tested in the “test” animal or cell, the term “suitable” implies there may be additional factors which could be considered necessary for a control animal or cell to be “suitable”. The term adds nothing to the claim language except ambiguity regarding the necessary factors required in order to constitute a “suitable” cell or animal, and should be simply dropped from the claim language.

Conclusion

Claims 1-2, 7-12, 23-27 and 56-58 are rejected. Claims 6, 50-54 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot can be reached on (703) 308-4003. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636



ggl
November 29, 2001

DAVID GUZO
PRIMARY EXAMINER
